

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Yves BONHOMME et al.

Serial No.:

Group Art Unit: 1615

Filed: March 25, 2004

Examiner: Susan T. TRAN

For: SOLID ORAL DOSAGE FORM COMPRISING A COMBINATION OF METFORMIN
AND GLIBENCLAMIDE

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
 - within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - within three months of the actual filing date of the national phase of a PCT application; OR
 - before the mailing of a first substantive office action (including after filing of an RCE).
- Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
 - a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- a final action under 37 C.F.R. § 1.113;
- termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
- a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. 10/329,426, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached were cited in an international search report dated _____.

Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
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Translation of other relevant information on foreign search report

[insert necessary translation here]

Other Information

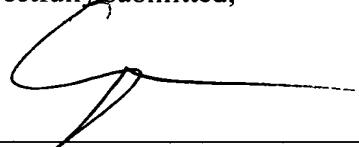
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A check for \$_____ covering the fee identified above is attached.

Please charge to Deposit Account No. 13-3402 \$_____ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney for Applicants

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Attorney Docket No.: MERCK-2593-R1-C1

Date: March 25, 2004

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | |
| | | | | Filing Date | March 25, 2004 |
| | | | | First Named Inventor | Yves BONHOMME et al. |
| | | | | Group Art Unit | 1615 |
| | | | | Examiner Name | Susan T. TRAN |
| <i>(use as many sheets as necessary)</i> | | | | | |
| Sheet | 1 | of | 3 | Attorney Docket Number | MERCK-2593-R1-C1 |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | |
| | B1 | WO | 97/17975 | | BARELLI et al. | 05/1997 | |
| | B2 | WO | 98/57634 | | | 12/1998 | |
| | B3 | WO | 97/17975 | | | 05/1997 | |
| | B4 | DE | 0 362 703 | | | 04/1990 | |
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| | | | | Examiner Name | Susan T. TRAN |
| Sheet | 2 | of | 3 | Attorney Docket Number | MERCK-2593-R1-C1 |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|---|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | C1 | Bi-Euglucon M Italian Package Insert, Repertorio Farmaceutico Italiano, 1998 (with English translation pp. 1-9) | | |
| | C2 | R. Vigneri, et al., Diabete & Metabolisme, vol. 17, pp. 232-234, "Treatment of NIDDM Patients With Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide", 1991 | | |
| | C3 | Linda Higginbotham, et al., The Medical Journal of Australia, pp. 154-156, "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics", Aug. 11, 1979 | | |
| | C4 | Iris J. Edwards, et al., Diabetes, vol. 46, No. 5, Suppl. 1, pp. 45A, "Combination Glipizide Gits/Metformin Treatment Reduces Low Density Lipoprotein Binding To Arterial Proteoglycans In NIDDM", 1997 | | |
| | C5 | William T. Cefalu, et al., Diabetes, vol. 45, Suppl. 2, pp. 201A, "Combination Glipizide Gits/Metformin Normalizes Glucose And Improves Insulin Sensitivity In Hyperinsulinemic Moderately Well Controlled NIDDM", 1996 | | |
| | C6 | John R. Crouse, et al., Circulation, vol. 94, No. 8, Suppl. 1508, Effects Of Combination Glipizide Gits/Metformin Treatment On Oxidizability Of LDL In Non-Insulin Dependent Diabetes Mellitus, 1996 | | |
| | C7 | W. T. Cefalu, et al., Diabetologia, vol. 39, Suppl. 1, pp. A231, "Insulin Sensitivity Is Improved After Glipizide Monotherapy And Combination With Metformin", 1996 | | |
| | C8 | Gerald M. Reaven, et al., Journal of Clinical Endocrinology and Metabolism, vol. 74, No. 5, pp. 1020-1026, Combined Metformin-Sulfonylurea Treatment Of Patients With Noninsulin-Dependent Diabetes In Fair To Poor Glycemic Control, 1992 | | |
| | C9 | CB Hollenbeck, et al., Diabetes, vol. 39, Suppl. 1, pp. 108A, "Combination Glipizide/Metformin Treatment In Non-Insulin Dependent Diabetes (NIDDM)", 1990. | | |
| | C10 | Press Release Sep. 30, 1999: Bristol-Myers Squibb Files New Drug Application for Novel Oral Antidiabetic Drug, 2 pp., 1999. | | |
| | C11 | Glucomide--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-6). | | |
| | C12 | Glibomet--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-7). | | |
| | C13 | Suguan M--Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., 1999 (with English translation pp. 1-9). | | |

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| | | | | Attorney Docket Number | MERCK-2593-R1-C1 |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | | |
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| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
| | C14 | Bi-Euglucon M13 Italian Package Insert, Repertorio Farmaceutico Italiano, 1 p., (with English translation pp. 1-9). | | T ² |
| | C15 | Blume et al., Drug Development and Industrial Pharmacy, 19(20), 2713-2741 (1993) | | |
| | C16 | PDR, 56 ed, 2002, "Alyburide" listing and Glucophage® and Glucovance® package inserts | | |
| | C17 | PDR, 52 ed, 1998, "Glyburide" listing, generic listings and Micronase®, Glynase® and Dia Beta® package inserts | | |
| | C18 | AU 42302/89 Abstract | | |
| | C19 | Al-Ahmed et al., "Bioscience Reports," Vol. 9, No. 3, 1989, 347-350. | | |
| | C20 | Letter dated April 1, 2002 from Ivax Pharmaceuticals, Inc. to Lipha, S.A. (assignee of U.S.P. 6,303,146) and Bristol-Myers Squibb (marketeer of Glucovance® covered by U.S.P. 6,303,146). | | |
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